REMARKS

Claims 1-2, 11-14, and 16-21 remain pending. By this amendment, Applicants amend Claims 1 and 2. Support for the amendments appears in the specification at pages 2 and 7. No new matter is introduced by the amendments. Applicants respectfully request reexamination and reconsideration of the application in view of these amendments and the remarks.

Double Patenting Rejection

The Examiner rejects Claims 1, 2, 11-14 and 16-21 under the judicially-created doctrine of obviousness-type double patenting as being unpatentable over Claims 3, 4, 9, 10, and 11 of U.S. Patent No. 6,326,357. The Examiner states that "[a]lthough the conflicting claims are not identical, they are not patentably distinct from each other because both are drawn to methods of treatment comprising administration of a composition comprising Mycobacterium cell wall complex (MCC) . . . wherein the Mycobacterium DNA (M-DNA) is preserved and complexed on the MCC." The Examiner's position is that the methods of the '357 patent and the currently-pending claims encompass the identical method steps, the same concentrations, and overlapping doses. The Examiner further asserts that the claimed cancer treatment of the '357 patent stimulates the production of IL-10, that it was known in the art that IL-10 is an anti-inflammatory cytokine, and that it would have been obvious that treatment with MCC would be effective for treating and preventing inflammation. The rejection is respectfully traversed.

A double patenting rejection of the obvious-type is analogous to a failure to meet the nonobviousness requirement of 35 U.S.C. § 103 except that the patent principally underlying the double patenting rejection is not considered prior art. Therefore, any analysis employed in an obvious-type double patenting rejection parallels the guidelines for analysis of a 35 U.S.C. § 103 obviousness determination. *See* MPEP 804 (citing *In re Braithwaite*, 379 F.2d 594 (CCPA 1967) and *In re Braat*, 937 F.2d 589 (Fed. Cir. 1991). In order to rely on a reference under 35 U.S.C. § 103, the reference must be analogous art,

or reasonably pertinent to the particular problem with which the inventor was concerned. *See* MPEP 2141.01(a) (citing *In re Oetiker,* 977 F.2d 1443, 1446 (Fed. Cir. 1992).

The Examiner admits that claims 3, 4, 9, 10, and 11 of the '357 patent are drawn to a method of treating *cancer*, while the claims pending in the present application are drawn to methods of treating and preventing *inflammation.* References describing methods for inhibiting the growth of cancer cells are not reasonably pertinent to the problem of preventing and treating various forms of inflammation. Inflammation is an entirely different disorder from cancer – it involves a number of different biological responses and thus, presents completely different treatment and prevention challenges. Patients could clearly be afflicted with cancer without exhibiting a trace of inflammation, and vice versa. The knowledge that the use of a composition to stimulate immune system cells to produce bioactive molecules, such as cytokines, and specifically, IL-10 (*see* claims 3, 9, 10, and 11 of the '357 patent) to inhibit growth of cancer cells simply cannot be characterized as teaching one of ordinary skill in the art (the field of inflammation research or treatment) that the composition will be useful to treat or prevent inflammation.

The '357 patent indicates that the treatment described stimulates the production of IL-10, however the Examiner's rejection fails to recognize that cytokines stimulate a vast number of biological responses aside from being an anti-inflammatory cytokine - mere examples in the '357 patent itself include promoting the maturation of leukocytes and inducing the secretion of interferon-gamma (see '357 patent, col. 1, lines 63- col. 2, line 4). Thus, in view of these remarks, Applicants respectfully assert that the claims of the pending application are patentably distinct from the '357 patent and respectfully request withdrawal of the rejection.

Claim Rejections – 35 U.S.C. § 102

The Examiner rejects Claims 1, 2, and 11-14 under 35 U.S.C. § 102(a) as being anticipated by *Bermudez* and *Champsi* (*Infect. Immun.*, 1997, v. 61, pp. 3093-3097) (hereinafter *Bermudez*). The Examiner states:

> Of particular interest, Bermudez & Champsi state, "[T]he antagonistic effect of IL-10 can play an important role in the kinetics of cytokine response following infection with M. avium" and "suppressive cytokines can be advantageous to the bacterium" (see p. 3096, left col.). Therefore, Bermudez & Champsi teach a method of administering to an animal an effective amount of a composition comprising a mycobacterial DNA preserved and complexed on a mycobacterial cell wall and a liquid pharmaceutically acceptable carrier wherein the effective amount is effective to induce the synthesis of cytokine IL-10. This method would effectively treat or prevent inflammation in an animal because the mycobacterium administered is effective to induce the synthesis of anti-inflammatory cytokine IL-10.

The Examiner further states that Applicants' arguments filed May 31, 2002 were not persuasive because the distinguishing features relied upon in those arguments were not recited in the rejected claims. Applicants have amended claims 1 and 2 (and thus, by the nature of their dependency, claims 11-14) to recite that the BCC is obtained from disrupted mycobacterium, support for which appears in the specification at page 2, lines 17-22 and Example 1 (page 7, lines 33). This clarifies that the BCC does not contain live mycobacterial cells, as opposed to the live *M. avium* used by *Bermudez*.

Moreover, the Examiner has failed to consider the teachings of the *Bermudez* reference as a whole. A prior art reference must be considered in its entirety, i.e., as a whole, including portions that would lead away from the claimed invention. *See* MPEP 2141.02 (citing *W.L. Gore & Assocs., Inc. v. Garlock, Inc.*, 721 F.2d 1540 (Fed. Cir. 1983) (emphasis added)). *Bermudez* relates to research regarding the role that *M. avium* plays with disseminated infection in patients with AIDS. The researchers infected animals with live *M. avium* cells, which were found to trigger IL-10 production. The researchers concluded that IL-10 plays a role in the pathogenesis of *M. avium* infection. The *Bermudez* reference simply does not seek to treat or prevent inflammation – a practitioner interested in inflammation treatment would not refer to it. In light of these arguments and amendments to the claims, Applicants respectfully request that the Examiner withdraw the rejection.

Claim Rejections – 35 U.S.C. § 112

The Examiner rejects Claims 1, 2, and 11-14 under 35 U.S.C. § 112, first paragraph as not being enabled. The Examiner states that while the specification is enabling for a method for treating inflammation comprising administration of a mycobacterial cell wall complex derived from *M. phlei* and *M. avium*, it does not reasonably provide enablement for the method of treating inflammation comprising administration of a mycobacterial cell wall complex derived from any other mycobacteria. Applicants traverse this rejection and request reconsideration and withdrawal thereof.

The Examiner is respectfully directed to Example 2 of the specification. In that example, Applicants clarify that the use of any other mycobacterial species can be used according to the invention. Thus, one of ordinary skill in the art would understand that the methods of the invention, and particularly, the preparation of MCC described in Example 1 can be used to prepare a composition using another mycobacterical species. It would not require undue experimentation to then simply deliver the composition to a patient in order to treat or prevent inflammation.

Representative examples together with a statement applicable to the genus as a whole are ordinarily sufficient to establish enablement if one skilled in the art would expect the claimed genus could be used in that manner without undue experimentation. *See* MPEP 2164.02. Additionally, with respect to undue experimentation, "the test is not merely quantitative, since a considerable amount of experimentation is permissible, if it is merely routine, or if the specification in question provides a reasonable amount of guidance with respect to the direction in which the experimentation should proceed." *See* MPEP 2164.06 (citing *In re Wands,* 858 F.2d 731 (Fed, Cir, 1988).

Experimenting with other species of myobacteria (even those not listed in the specification) would not be undue experimentation. The methods for preparation and delivery are described in the application. Particularly because the Examiner deems the

level of skill in art to be "high," it would be merely routine for an accomplished scientist to test various species of mycobacteria in order to treat or prevent inflammation according to the presently-claimed invention.

Accordingly, Applicants assert that the claims are now in condition for allowance and respectfully request that the application be passed to issuance. If the Examiner believes that any informalities remain in the case which may be corrected by Examiner's amendment, or that there are any other issues which can be resolved by a telephone interview, a telephone call to the undersigned attorney at (404) 815-6147 is respectfully solicited.

Respectfully submitted,

Kristin Mallatt

Kristin D. Mallatt
Reg. No. 46,895

OF COUNSEL:

KILPATRICK STOCKTON LLP
1100 Peachtree Street
Suite 2800
Atlanta, Georgia, 30309-4530
404.815.6147

VERSION OF AMENDMENTS WITH MARKINGS SHOWING CHANGES

Added text is marked with underline. Deleted text is marked with [square brackets].

In the Specification:

Kindly amend the first full paragraph on page 2 with the following paragraph:

The present invention satisfies the above need by providing a mycobacterial deoxyribonucleic acid (B-DNA) preserved and complexed on a mycobacterial call wall [(MCC)] (BCC), wherein the BCC is effective in treating an inflammation in an animal having an inflammation. More particularly, the present invention provides a *Mycobacterium phlei (M. phlei)* deoxyribonucleic acid (M-DNA) preserved and complexed on *M. phlei* cell wall (MCC), wherein the MCC is effective in treating an inflammation in an animal having an inflammation.

In the Claims:

Please amend Claim 1 as follows:

1. (Amended Twice) A method for treating inflammation in an animal having inflammation, comprising administering to the animal an effective amount of a composition comprising:

(a) a mycobacterial deoxyribonucleic acid obtained from a disrupted mycobacterium, the mycobacterial deoxyribonucleic acid preserved and complexed on a mycobacterial cell wall (BCC); and[;]

(b) a pharmaceutically acceptable carrier, wherein the amount is effective to treat the inflammation.

Please amend Claim 2 as follows:

2. (Amended Twice) A method for preventing inflammation in an animal, comprising administering to the animal an effective amount of a composition comprising:
(a) a mycobacterial deoxyribonucleic acid obtained from a disrupted mycobacterium, the mycobacterial deoxyribonucleic acid preserved and complexed on a mycobacterial cell wall (BCC); and[;]

(b) a pharmaceutically acceptable carrier, wherein the amount is effective to prevent the inflammation.